Vaccines other than those produced in animal skins should be tested for bacterial and fungal sterility according to the requirements given in Part A, section 5, of the revised Requirements for Biological Substances No.6 (Requirements for the Sterility of Biological Substances) (16).

5.3 Virus titration

The vaccinia titre should be determined using assays which include a reference preparation. Dried vaccine shall be reconstituted to the form in which it is to be used for human inoculation before the test is made. The minimum virus titre per ml is 8.0 log10 pock forming units, or the validated equivalent in plaque forming units or TCID50 units, unless a lower titre is justified by clinical study, and this should be maintained to the end of the shelf-life of the batch.

The 95% confidence intervals of the assays should not differ by a factor of more than 0.5log10 from the estimated number of infectious units in the vaccine.

For the test of virus concentration in cell cultures, an international collaborative study is in progress that will provide valuable information on the most appropriate method to recommend. Results of this study are expected in 2003.

5.4 Accelerated degradation test

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Representative final containers of the vaccine should be incubated at an elevated temperature for a defined period of time. For freeze-dried vaccines this should be 37c for 4 weeks. For non-lyophilized vaccines, other temperatures and time periods may have to be determined on a case by case basis by the national regulatory authority

The purpose of this test is to show that each new batch of vaccine is consistent, when exposed to heat stress, with the batches that were tested in real- time stability studies and used to determine the shelf-life of the vaccine.

The total virus content in both exposed and unexposed vials should be determined concurrently with that of a reference preparation. The vaccine passes the test when the loss on exposure is not greater than a factor of 1.0 log10 infectious units per human dose, and the residual titre after heating is greater than that specified in part A, section 5.3.

5.5 Preservative content

Where appropriate, each filling lot should be assayed for preservative content, if this has not been done for the final bulk. The method used and content permitted should be approved by the national regulatory authority.

5.6 Endotoxin content

Each filling lot should be tested for endotoxin, if this has not been done on the final bulk. The method used and content permitted should be approved by the national regulatory authority.

5.7 Test for pH

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The pH of each filling lot should be determined and be within limits approved by the national regulatory authority.

5.8 Protein content

The protein content of each filling lot, if not done on the final bulk, should be determined and be within limits approved by the national regulatory authority.

5.9 Ovalabumin content

For vaccines produced in embryonated eggs only, the ovalbumin content of each filling lot, if not done on the final bulk, shall be determined and be within limits approved by the national regulatory authority.

5.10 Residual moisture

The residual moisture content of each filling lot of freeze-dried vaccine shall be determined and be within limits approved by the national regulatory authority.

5.11 General safety (innocuity) test

Each filling lot should be tested for unexpected toxicity (sometimes called abnormal toxicity) using a general safety (innocuity) test approved by the national regulatory authority.

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This test may be omitted for routine lot release once consistency of production has been well established to the satisfaction of the national control authority and when good manufacturing practices are in place. Each lot, if tested, should pass a test for abnormal toxicity. However it should be noted that preliminary experiments may be needed to determine the sample volume to use for this product in this test.

6. RECORDS

The recommendations given in "Good manufacturing practices for biological products"(9) should apply.

7. SAMPLES

The requirements given in "Good manufacturing practices for biological products"(9) should apply.

8. LABELLING

The requirements given in "Good manufacturing practices for biological products"(9) should apply with the addition of the following:

The label on the container or package should include the following information:

- the designation of the strain of vaccinia virus contained in the vaccine,
- the minimum amount of virus contained in one ml,
- the substrate used for the preparation of the vaccine,
- the nature and amount of any stabilizer, preservative or additives present in the vaccine

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- the nature and amount of any stabilizer, preservative or additives present in the diluent

No vaccine should be released for distribution without an adequate indication of the expiry date of the vaccine. This may be on the primary or secondary packaging.

It is desirable for the label to carry the name both of the producer and of the source of the bulk material, if the producer of the final vaccine did not prepare it. The nature and amount of the antibiotics present in the vaccine, if any, may be included.

9. DISTRIBUTION AND SHIPPING

The requirements given in "Good manufacturing practices for biological products"(9) should apply.

10. STORAGE AND EXPIRY DATE

The statements concerning storage temperature and expiry date appearing on the primary or secondary packaging should be based on experimental evidence and should be submitted for approval to the national regulatory authority.

10.1 Storage conditions

Before being released by the manufacturing establishment, all vaccines in final containers should be kept continuously in the frozen state at a temperature below -20 °C.

The maximum duration of storage should be fixed with the approval of the national regulatory authority and should be such as to ensure that the minimum titre specified on the label of the

container (or package) will still be maintained after release by the manufacturing establishment until the end of the shelf life, if the conditions under which the vaccine is stored are in accordance with what is stated on the label. The maximum duration of storage at 2-8 °C or below -20 °C may be specified.

Since vaccinia virus batches may be stockpiled for contingency situations then very long-term storage may be envisaged. Under these exceptional circumstances it is permissible for batches to be retested at defined intervals for extension of the storage period. The retesting should involve the accelerated degradation test given in part A, section 5.4. If the batch complies with the specifications given in part A, section 5 then the storage period can be extended by the same amount as the original period.

10.2 Expiry date

The expiry date should be fixed with the approval of the national control authority and should relate to the date of the last satisfactory determination, performed in accordance with Part A, section 5.3, of virus concentration, i.e., the date on which the test system was inoculated.

PART B. RECOMMENDATIONS FOR NATIONAL REGULATORY AUTHORITIES

1. General

The general recommendations for national regulatory authorities given in "Guidelines for national authorities on quality assurance for biological products"(19), which specify that no new biological substance should be licensed until consistency of production has been established, should apply. The detailed production and control procedures and any significant changes in them should be discussed with and approved by the national regulatory authority. The national regulatory authority

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should obtain the International Standard for virus titre and, where necessary, establish national working reference preparations by comparison with this preparation.

2. RELEASE AND CERTIFICATION

A vaccine lot should be released only if it satisfies Part A of the present Recommendations. Before any vaccine lot is released from a manufacturing establishment, the requirements for consistency of production given in "Guidelines for national authorities on quality assurance for biological products"(19) should be met.

A statement signed by the appropriate official of the national control laboratory should be provided if requested by a manufacturing establishment and should certify whether or not the lot of vaccine in question meets all national requirements as well as Part A of the present Requirements. The certificate should further state the date of the last satisfactory determination of virus concentration, the lot number, the number under which the lot was released, and the number appearing on the labels of the containers. In addition, a copy of the official national release document should be attached.

The purpose of the certificate is to facilitate the exchange of smallpox vaccine between countries. National Regulatory Authorities should consider re-certification of vaccine lots at the time of distribution.

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原料ゴム特性一覧表

〔記号は◎＝優、○＝良、△＝可、×＝不可〕

ASTM略号（一般名）	化学構造	商品名（メーカー）	原料ゴムの性質	配合ゴムの物理的性質および耐性																配合ゴムの耐油・耐溶剤性										配合ゴムの耐酸・耐アルカリ性						備考
			臭気	可能なカタサ範囲JIS	引張強さ（kg/cm²）	伸び（%）	反バツ弾性	引裂	耐摩耗性	耐屈曲亀裂性	耐熱性（使用温度℃）（最高）	耐寒性（脆化温度℃）	耐老化性	耐光性	耐オゾン性	耐炎性	電気絶縁性（体積固有抵抗 Ω-cm）	ガス透過性	耐放射線性	ガソリン軽油	ベンゼントルエン	トリクレン	アルコール	エーテル	ケトン（MEK）	酢酸エチル	ジエステル潤滑系油	リン酸塩圧力作動系油	ケイ酸塩圧力作動系油	水	有機酸	強酸	弱酸	強アルカリ	弱アルカリ	
N R（天然ゴム）	ポリイソプレン	スモークド・シート ペール・クレープ エア・ドライド・シート等	△～○	10～100	30～300	100～1000	◎	◎	○	◎	120	−50～−70	○	○	×	×	10^{10}～10^{15}	○	△～○	×	×	×	○	×	△～○	×～△	×～△	×～△	×	◎	×	△	○	○	○	通常の天然ゴムの他に加工性をよくしたSPラバーやクレイのマスターバッチがある。
I R（合成天然ゴム（イソプレンゴム））	ポリイソプレン	ナットシン（グッドイヤー） カリフレックスIR（シエル）他	○	20～100	50～200	100～1000	◎	○	○	◎	120	−50～−70	○	○	×	×	10^{10}～10^{15}	○	△～○	×	×	×	◎	×	△～○	×～△	×～△	×～△	×	◎	×	△	○	○	○	天然ゴムと構造は全く同一であるが加工性がよく、加硫が若干おそい。
S B R（スチレンゴム）	ブタジエン・スチレン共重合体	JSR（日本合成ゴム） ニポール（日本ゼオン） クライレン（ポリマー）他	○	30～100	50～200	100～800	○	△	◎	○	120	−30～−60	○	○	×	×	10^{10}～10^{15}	△	○	×	×	×	◎	×	△～○	×～△	×	×	×～△	◎	×	△	○	○	○	スチレンの結合量の大きいハイスチレンというタイプもある。
I I R（ブチルゴム）	イソブチレン・イソプレン共重合体	エンジェイ・ブチル（エッソ） ポリサー・ブチル（ポリマー） ペトロテックス・ブチル（ペトロテックス）他	○	20～90	50～150	100～800	△	○	○	◎	150	−30～−55	◎	◎	◎	×	10^{16}～10^{18}	◎	×	×	△～○	×	◎	△～○	◎	◎	△	○	△	◎	△～○	◎	◎	◎	◎	ハロゲン化（塩素化、臭素化）という特殊なタイプもある。
B R（ブタジエンゴム）	ポリブタジエン	BR01（日本合成ゴム） ジエン（旭化成） ニポールBR（日本ゼオン） タクテン（ポリマー）他	○	30～100	20～200	100～800	◎	○	◎	△	120	−73	○	○	×	×	10^{14}～10^{15}	○	×	×	×	×	◎	×	△～○	×～△	×～△	×～△	×	◎	×	△	○	○	○	高シス型が一般的であるがジエンのように低シス型のものもある。
EPM (EPDM)（エチレン・プロピレンゴム）	エチレン・プロピレン共重合体（三元共重合体）	ロイヤレン（USラバー） デュートラル（モンテカチニ） ノーデル（デュポン） エンジェイEPR（エッソ）他	△～○	30～90	50～200	100～800	○	△	○	○	150	−40～−60	◎	◎	◎	×	10^{12}～10^{15}	○	×	×	△	×	◎	○	◎	◎	×～△	○	×～○	◎	×	○	◎	◎	◎	エチレン・プロピレンターポリマー（EPDM）が、一般的になりそうである。
N B R（ニトリルゴム）	ブタジエン・アクリロニトリル共重合体	ハイカー（日本ゼオン） JSR（日本合成ゴム） クライナック（ポリマー） ペルブナンN（バイエル） パラクリル（USラバー）〃	○	15～100	60～250	100～800	○	○	◎	○	130	−10～−20	◎	○	×	×～△	10^{8}～10^{10}	○	△～○	◎	×～△	×	◎	×～△	×	×～△	×～○	×	△	◎	×～△	○	○	○	○	ニトリル含有量によって耐油性の異るグレードのものが多くある。
C R（クロロプレンゴム）	ポリクロロプレン	ネオプレン（昭和ネオプレン） 電化クロロプレン（電気化学） ペルブナンG（バイエル）他	○	10～90	50～250	100～1000	◎	○	○～◎	○	130	−35～−55	◎	◎	◎	○	10^{10}～10^{12}	○	△～○	○	×	×	◎	×～△	△～○	×	×	×	○	◎	×～△	○	◎	◎	◎	イオン変性型とそうでないタイプのものがある。
C S M（ハイパロン）	クロロ・スルフォン化ポリエチレン	ハイパロン（デュポン）	○	50～90	70～200	100～500	○	○	◎	○	150	−20～−60	◎	◎	◎	○	10^{14}	◎	△～○	△	×～△	×～△	◎	×	△～○	×	×	×	○	◎	△	◎	◎	◎	◎	非加硫型と呼ばれるハイパロン45というのもある。
U（ウレタンゴム（ポリウレタン））	ポリウレタン	パンレックス（日本ライヒ）、アジプレン（デュポン）、ブルコラン、ウレパン（バイエル） ジエンタン（G・タイヤ）、エラストサン（チオコール）、エステン（日本ゼオン）	○	10～100	200～450	300～800	◎	◎	◎	◎	80	−30～−60	○	◎	◎	×～△	10^{9}～10^{12}	○	○	◎	×～△	△～○	△	×	×	△	×	×	×	△	×	×	△	×	×	キャスチングタイプ、ミラブルタイプ、熱可塑性タイプの3種類がある。
T（多硫化ゴム）	有機ポリサルファイド	チオコール（チオコール）	×	30～90	30～150	100～700	△	×～△	×～△	×	80	+10～−40	○	◎	◎	×	10^{11}	◎	△～○	◎	◎	△～○	◎	×～△	◎	△～○	○	△	×～△	○	×	×	△	△	△	ドライラバーよりも液状品の方が用途が多い。
SI（シリコンゴム（ケイ素ゴム））	有機ポリシロキサン	信越シリコン（信越化学） 東芝シリコン（東芝） UCCシリコン，ユカジル（UCC） シラスチック（ダウ）	○～◎	30～90	40～100	60～600	◎	×～△	×～△	×～○	280	−70～−120	◎	◎	◎	×～○	10^{11}～10^{16}	△	△～◎	×～△	×～△	×～○	◎	×～△	○	△～○	×～△	◎	×	○	○	△	○	◎	◎	原料から出発することはまれで、市販品はベースかコンパウンドになっている。
F P M（フッ素ゴム）	6フッ化プロピレン・フッ化ビニリデン共重合体	バイトン（デュポン） フローレル（3M）	○	50～90	70～200	100～500	△	○	◎	○	300	−10～−50	◎	◎	◎	◎	10^{13}～10^{16}	◎	△～○	◎	◎	○	◎	×～△	×	×	△～○	△	◎	◎	×	◎	◎	×	△	非常に高価
ACM, ANM（アクリルゴム）	アクリル酸エステル共重合体	ハイカー4021（グッドリッチ） チアクリル（チオコール） シアナアクリル（シアナミド）他	△～○	40～80	70～120	100～600	△	△	○	○	180	0～−30	◎	◎	◎	×～△	10^{8}～10^{10}	○	×～○	◎	×	×	×	×	×	×	○	×	○	△	×	△	○	△	○	色々なタイプの共重合体があり、夫々性質が異る。
E V A（エチレン・酢ビゴム）	エチレン・酢酸ビニル共重合体	レバプレン（バイエル） エルバックス（デュポン）	○	50～90	70～200	100～600	○	○	○	○	200	−20～−30	◎	◎	◎	×	10^{13}～10^{14}	◎	○	×	×	×	△	×	×	×	×	×	×	◎	△	△～○	○～◎	◎	◎	エルバックスは熱可塑性で、主としてプラスチックブレンドに用いられる。